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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER	
ZEMAN, M	

ART UNIT	PAPER NUMBER
1631	3

DATE MAILED: 09/05/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/351,296	Applicant(s) SEIDEL ET AL.	
	Examiner Mary K Zeman	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1)☒ Responsive to communication(s) filed on *12 July 1999* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-28* is/are pending in the application.

4a) Of the above claim(s) *12 and 14-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11,13 and 17-28* is/are rejected.

7)☒ Claim(s) *18-27* is/are objected to.

8)☒ Claims *11-28* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☒ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☐ received.

2.☒ received in Application No. (Series Code / Serial Number) *08/598,993* .

3.☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1631.

Claims 11-28 are pending in this application. Claims 1-10 were canceled by preliminary amendment.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 11, 12 and 17-28, drawn to peptides of the HCV hypervariable region, SEQ ID NO:s 1-10, classified in class 530, subclass 300.

II. Claims 11, 13 and 17-28, drawn to peptides of the HCV NS4 region, SEQ ID NO:s 11-16, classified in class 530, subclass 300.

III. Claims 11, 14 and 17-28, drawn to peptides of the HCV NS5 region, from 2217-2236, SEQ ID NO:s 17-22, classified in class 530, subclass 300.

IV. Claims 11, 15 and 17-28, drawn to peptides of the HCV NS5 region from 2402-2419, SEQ ID NO:s 23-24, classified in class 530, subclass 300.

V. Claims 11, 16 and 17-28, drawn to peptides of the HCV NS5 region from 2345-2357, SEQ ID NO:s 25-30, classified in class 530, subclass 300.

The inventions are distinct, each from the other because:

Each group of peptides from differing regions of the HCV polyprotein has differing biological properties which are not predictable. Knowledge of how a peptide from the

hypervariable region of HCV acts in a detection assay does not speak to the antigenicity or effectiveness of any other peptide from a differing region of HCV in the same assay. Each of the peptides has differing structures, and between the groups, there is no common structure or functional feature such that all of the peptides are linked. Each peptide sequence requires a substantial amount of searching, such that a search of all the encompassed polypeptides would pose an undue burden upon the examiner if not restricted.

Because these inventions are distinct for the reasons given above and the search required for Group I sequences is not required for Group II-V sequences, restriction for examination purposes as indicated is proper.

During a telephone conversation with Richard Berman on 6/26/00 a provisional election was made with traverse to prosecute the invention of Group II, claims 11, 13 and 17-28, SEQ ID NO: 11-16. Affirmation of this election must be made by applicant in replying to this Office action. Claims 12, and 14-16 (SEQ ID NO: 1-10 and 17-30) are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d) to DE 195 04 302.2, filed 2/9/95. The certified copy has been filed in parent Application No. 08/598993, filed on 2/9/96.

This application is a continuation of Application Serial No: 08/845,936, filed 4/28/97, which is a continuation of Application Serial No: 08/598,993, filed 2/9/96.

Information Disclosure Statement

The Information Disclosure Statement filed with the application has been considered, and an initialed copy of that form is enclosed.

Claim Objections

Claims 18-27 are objected to because of the following informalities: these claims all depend ultimately from canceled claim 1. They will be examined to the extent they can depend from claim 11, the only remaining independent claim. Claims 1-10 were canceled by preliminary amendment. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 24-27 provide for the use of peptides in various assays, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 24-27 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 11, 13 and 17-23 are rejected under 35 U.S.C. 101 because they read on products of nature, proteins of an intact virus. It is suggested that Applicant amend the product claims to indicate a "hand of Man" aspect, such as "A purified peptide comprising..." or "an isolated peptide comprising..."

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 28 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 5,935,778. Although the conflicting claims are not identical, they are not patentably distinct from each other because each step recited within the method is the same as each step recited in the method of claim 1 of the '778 patent. The claims of the patent encompass the use of the particular peptides of claim 11 in that method, and the specific method using the particular HCV peptides renders obvious the generic method utilizing any antigens.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who

has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 11, 13, 17- 20, 24 and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Wang et al. (USP 5,582,968).

The claims are drawn to peptides comprising an immunologically active region which comprises any of SEQ ID NO: 11-16. The immunologically active region is from 9-30 amino acids in length, is able to be bound to a solid phase, and can be used in methods of detecting HCV antibodies, and HCV infection is a patient sample.

Wang et al. (USP 5,582,968) discloses SEQ ID NO: 8 which is 100% identical to the immunologically active region identified as SEQ ID NO: 11. The peptides can be linked to immunologically inactive spacer or linker regions, can be bound to a solid phase (see the paragraph bridging columns 6 and 7), and be used in methods of detecting HCV antibodies, and HCV infection in a patient sample (columns 11-12).

Claims 11, 13, 17-20, 24, 25 and 27 are rejected under 35 U.S.C. 102(e) as being anticipated by Wang et al. (USP 5,747,239).

Claim 27 adds the limitation that the peptides are used to serologically type the sample for the strain of HCV.

Wang et al. (USP 5,747,239) discloses SEQ ID NO: 22 which is 100% identical to the immunologically active region identified as SEQ ID NO: 11. The peptides can be linked to immunologically inactive spacer or linker regions, can be bound to a solid phase (columns 17-18), and be used in methods of detecting HCV antibodies, and HCV infection in a patient sample (column 21, and the examples). Wang also teaches how to use peptides, such as the peptide of

SEQ ID NO: 22 to identify the serotype of the antibodies to the HCV virus which are present in a patient sample (column 55 lines 10-11).

Claims 11 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Inchauspe et al. (1991 PNAS USA vol 88 pages 10292-10296).

Inchauspe et al. (1991 PNAS USA vol 88 pages 10292-10296) discloses an HCV polyprotein that comprises an immunologically active portion which is 100% identical to SEQ ID NO: 12 (aa1738-1759 of the polyprotein). As the claim recites peptides comprising the particular region, the polyprotein of Inchauspe et al. anticipates the claims.

Claims 11, 13, 17, 18, 24, and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Okayama et al. (USP 5,847,101).

Okayama et al. (USP 5,847,101) discloses SEQ ID NO: 46 which has 21 consecutive amino acids which are identical to the immunologically reactive region identified as SEQ ID NO: 13. This sequence meets the limitation wherein the immunologically active region comprises at least 6 amino acids of the particular SEQ ID NO 13. The peptides are used in diagnostic assays for detecting antibodies present in patient serum, detection of infection, and serotyping of the infecting virus (see column 18 for assays).

Claims 11, 13, 24 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 06102273 (4/15/94).

JP 06102273 A (Published April 15, 1994) discloses an HCV antigen (R52737) which comprises a region (aa134-155) that is 100% identical to the immunologically reactive region identified as SEQ ID NO: 13. This peptide is used in assays to detect infection with HCV, and to detect antibodies present in patient samples.

Claims 11, 13, 24 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 05176774 (7/20/93).

JP 05176774 A (Published July 20, 1993) discloses an HCV antigen (W41741) which comprises a region (aa135-156) that is 100% identical to the immunologically reactive region identified as SEQ ID NO: 13. This peptide is used in assays to detect infection with HCV, and to detect antibodies present in patient samples.

Claims 11, 13, 24 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 04179482 (6/26/92).

JP 04179482 A (Published June 26, 1992) discloses an HCV antigen (R25863) which comprises a region (aa135-156) that is 100% identical to the immunologically reactive region identified as SEQ ID NO: 13. This peptide is used in assays to detect infection with HCV, and to detect antibodies present in patient samples.

Claims 11 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Okamoto et al. (1991 Journal of General Virology Vol 72 pages 2607-2704).

Okamoto et al. (1991 Journal of General Virology Vol 72 pages 2607-2704) discloses an HCV polyprotein that comprises an immunologically active portion which is 100% identical to SEQ ID NO: 14 (aa1742-1763 of the polyprotein). As the claim recites peptides comprising the particular region, the polyprotein of Okamoto et al. anticipates the claims.

Claims 11 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Okamoto et al. (1992 Virology Vol 88 pages 331-341).

Okamoto et al. (1992 Virology Vol 88 pages 331-341) discloses an HCV polyprotein that comprises an immunologically active portion which is 100% identical to SEQ ID NO: 15 and one that is identical to SEQ ID NO: 16 (aa1742-1763 of the polyprotein). As the claim recites peptides comprising the particular region, the polyprotein of Okamoto et al. anticipates the claims.

Claims 11, 13, 17, 18, 24, and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Okamoto et al. (USP 5,428,145).

Okamoto et al. (USP 5,428,145) discloses SEQ ID NO: 5 which comprises a region which has 22 consecutive amino acids which are identical to the immunologically reactive region identified as SEQ ID NO: 14. Okamoto et al. further disclose SEQ ID NO: 8 which comprises a region having 100% identity to SEQ ID NO: 15. The peptides are used in diagnostic assays for detecting antibodies present in patient serum, and detection of infection (column 5 lines 40-56, and columns 11-12). As the claim recites peptides comprising the particular region, the polyprotein of Okamoto et al. anticipates the claims.

Claims 11 and 13 are rejected under 35 U.S.C. 102(e) as being anticipated EP 435 229 (7/3/91).

EP 435 229 (7/3/91) discloses an HCV peptide (12755) that comprises an immunologically active portion which is 100% identical to SEQ ID NO: 16. As the claim recites peptides comprising the particular region, the peptide EP 435 229 anticipates the claims.

Claims 11 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Greene et al. (1995 Journal of General Virology Vol 76 Pt 1 pages 211-215).

Greene et al. (1995 Journal of General Virology Vol 76 Pt 1 (January) pages 211-215) disclose HCV NS4 proteins that comprises an immunologically active portion which is 100% identical to SEQ ID NO: 11, 13, 14 and 16, and a protein that comprises at least 6 consecutive amino acids from SEQ ID NO: 12. As the claim recites peptides comprising the particular region, the proteins of Greene et al. anticipates the claims.

Claims 11, and 17-27 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 93/18054 (September 16, 1993 PTO-1449).

Claims 21 and 22 stipulate that the solid phase binding region is biotin, and that the peptides comprise a marker group.

WO 93/18054 discloses HCV NS4 peptides that meet the limitations of claim 11 (pages 14, 15, 19) which comprise the marker and solid phase binding agent biotin. These biotinylated

peptides are bound to a solid phase coated with streptavidin (page 23-24), and used in a variety of immunoassay formats (pages 24-26, 43-48, 54-56).

Conclusion

No Claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (703) 305-7133. The examiner can be reached between the hours of 7:30 am and 5:00 pm Monday through Thursday, and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at (703) 308 4028.

The fax number for this Art Unit is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center receptionist whose telephone number is (703) 308-0196.

mkz
August 31, 2000

Mary Zeman
Examiner, 1631